



Air Toxics Risk Assessment 101



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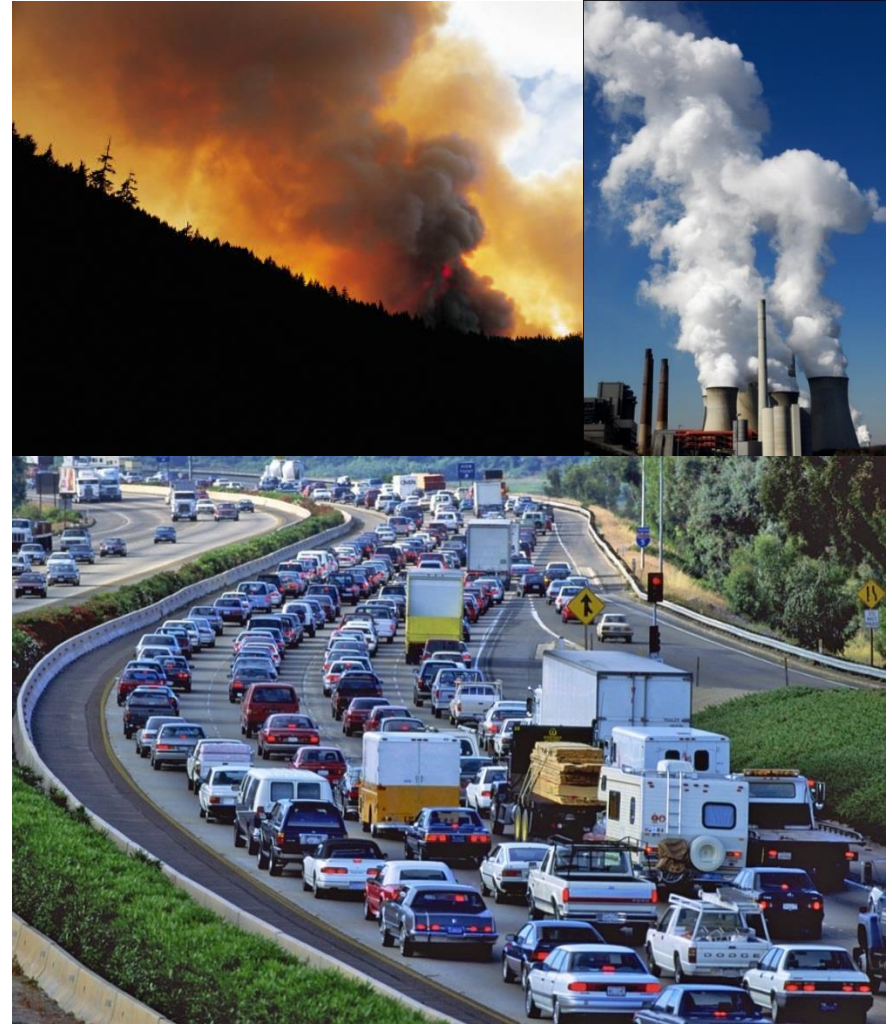


EPA is an environmental compliance organization.

The mission of the EPA is to protect human health and to safeguard the natural environment — air, water, and land — upon which life depends.

The Risk Assessment process is a compliance tool used by the EPA to evaluate pollutant releases based on each chemical's toxic properties and the potential for human exposure.

The Agency uses this process to evaluate the risks posed to human health from man-made and naturally occurring toxic air pollutants.



Risk-based Programs: General Comparison

	CDC ATSDR	EPA Superfund	EPA Air Toxics
Data Source	SF Sampling	SF Sampling	Air Toxics Sampling
Risk-based	Yes	Yes	Yes
Application	Public Health Assessment Recommendations	RI(w/RA)-FS (Cleanup)	Air Toxics RA Enforcement

- ❖ Data Source refers to the source of the sampling data used in the program's analysis.
- ❖ Risk-based refers to the use of a Risk Assessment approach which results in cancer- and non-cancer-based criteria.
- ❖ Application refers to how the risk-based answer is used in decision making.

Air Pollution Sources Are Everywhere

Where do we Start???



Courtesy of Sustaining the Environment and Resources for Canadians

Air Pollutant Focus Categories

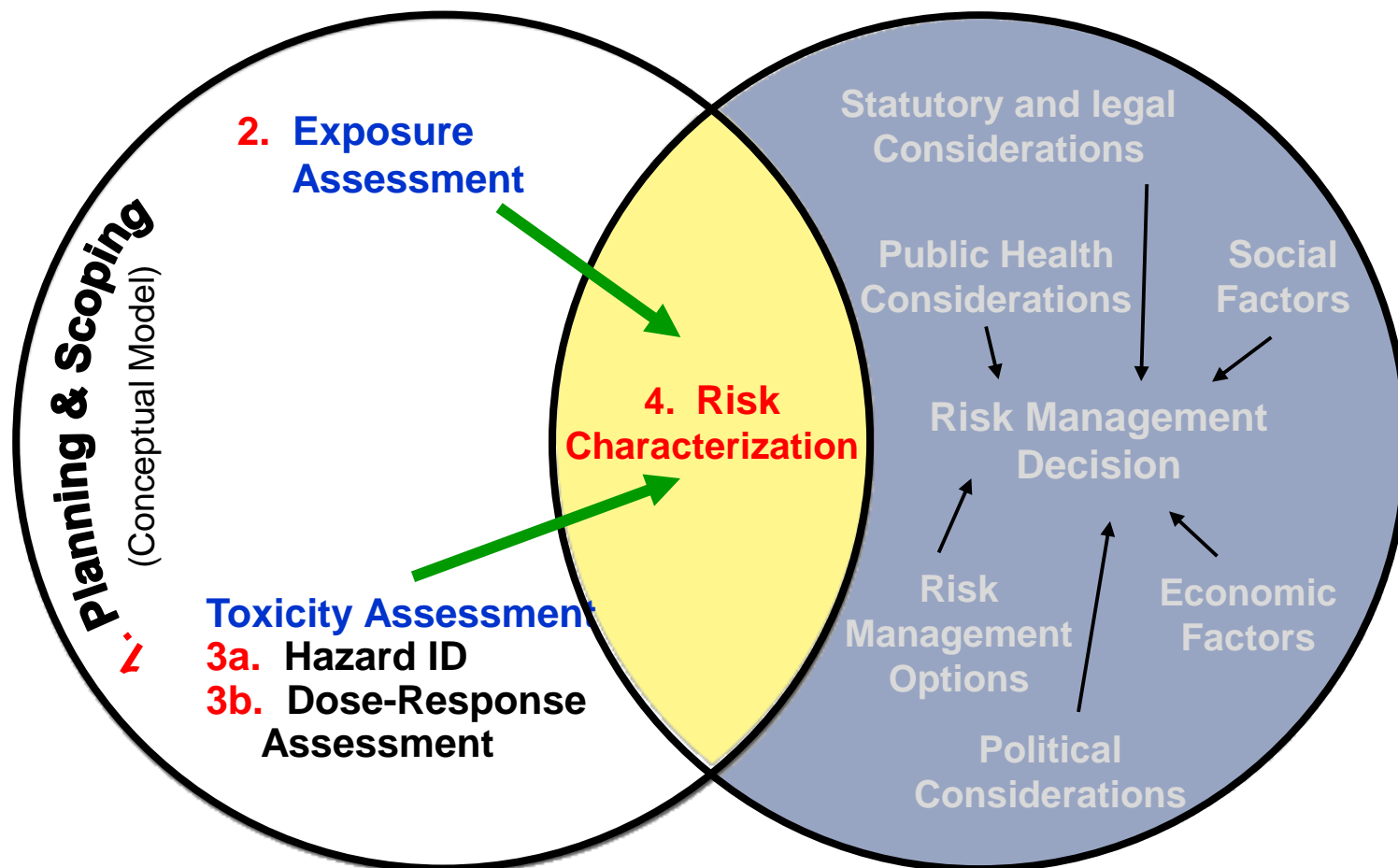
- **National Ambient Air Quality Standards (NAAQS – 6 Chemicals)**
- **Air Toxics (187 Hazardous Air Pollutants or HAPs)**

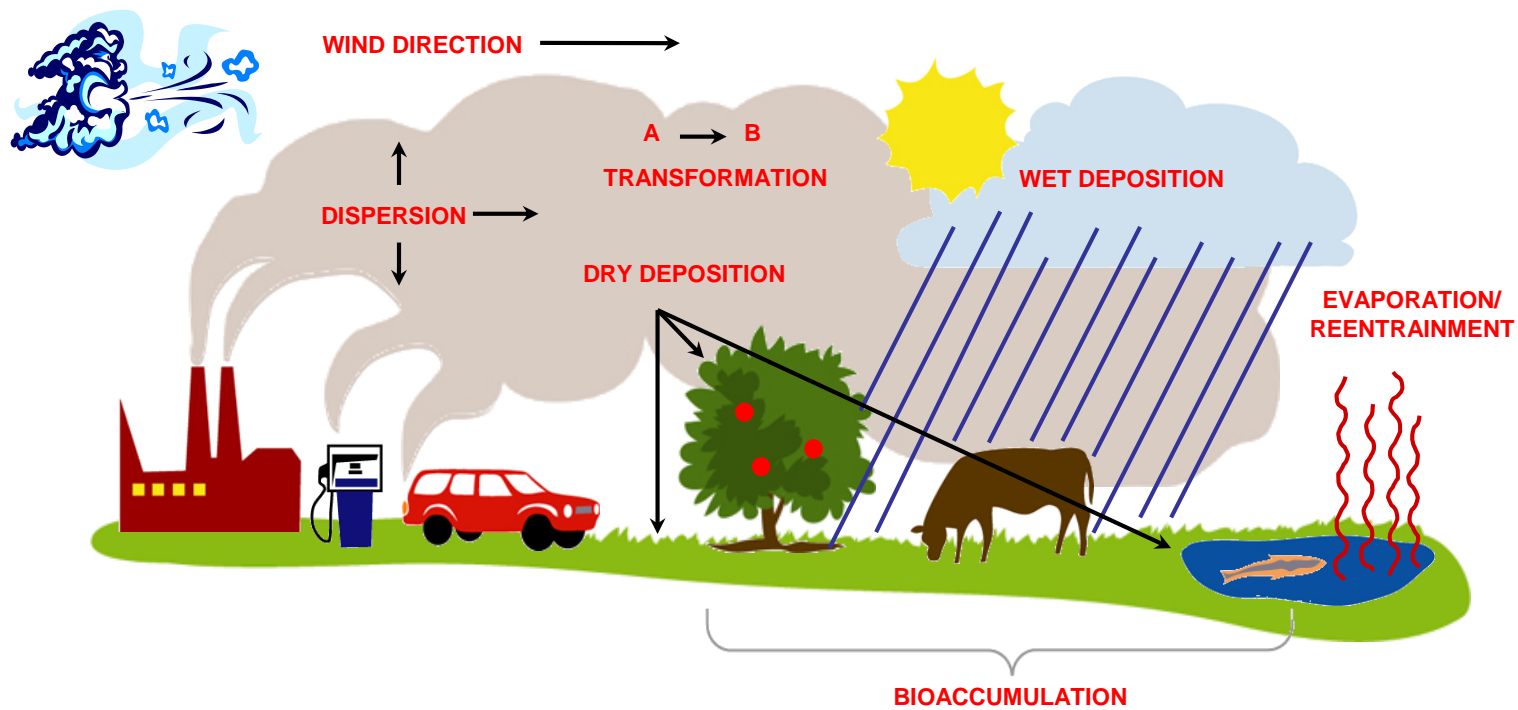


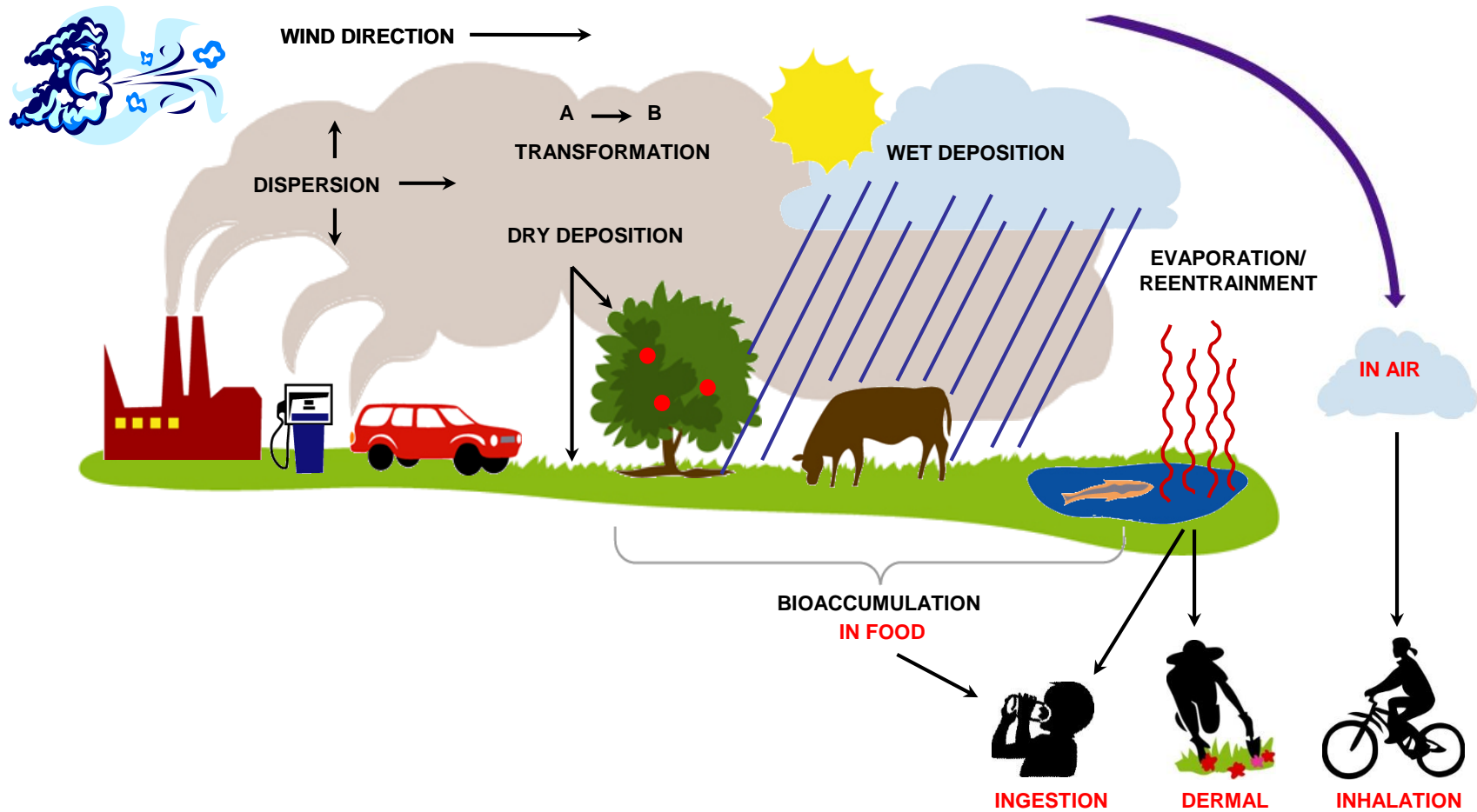
Modified NAS's Risk Paradigm For Air Toxics

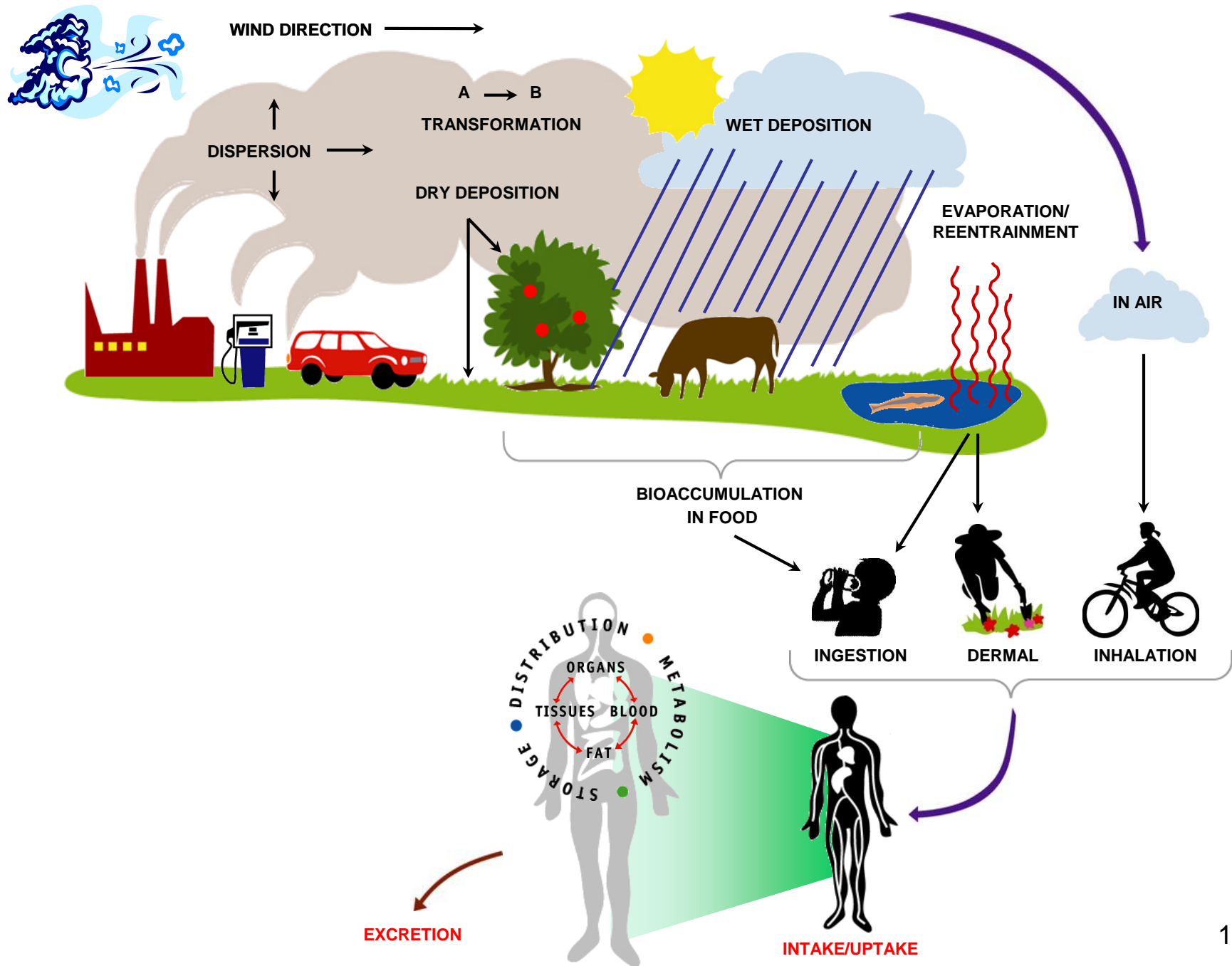


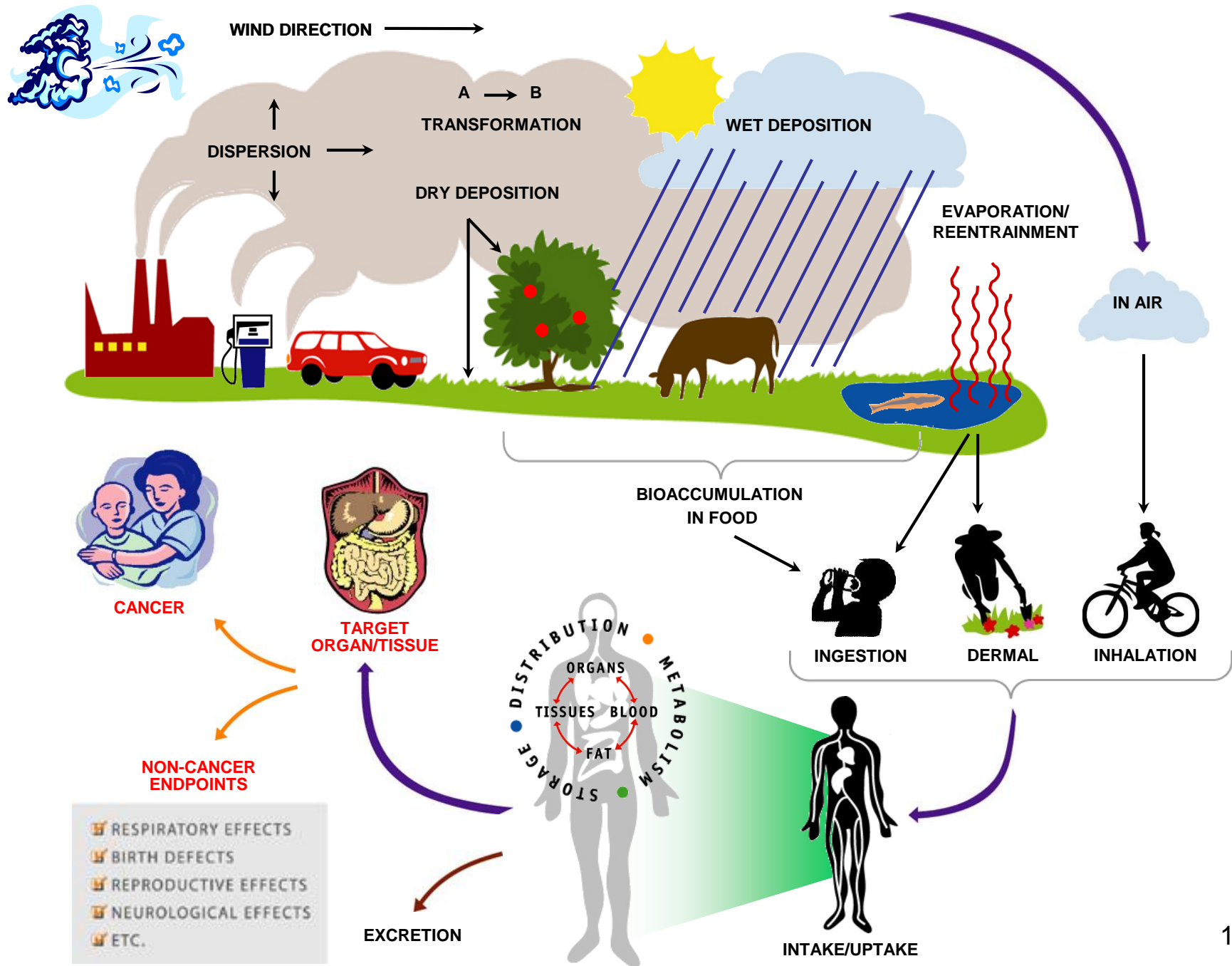
Risk Assessment Risk Management







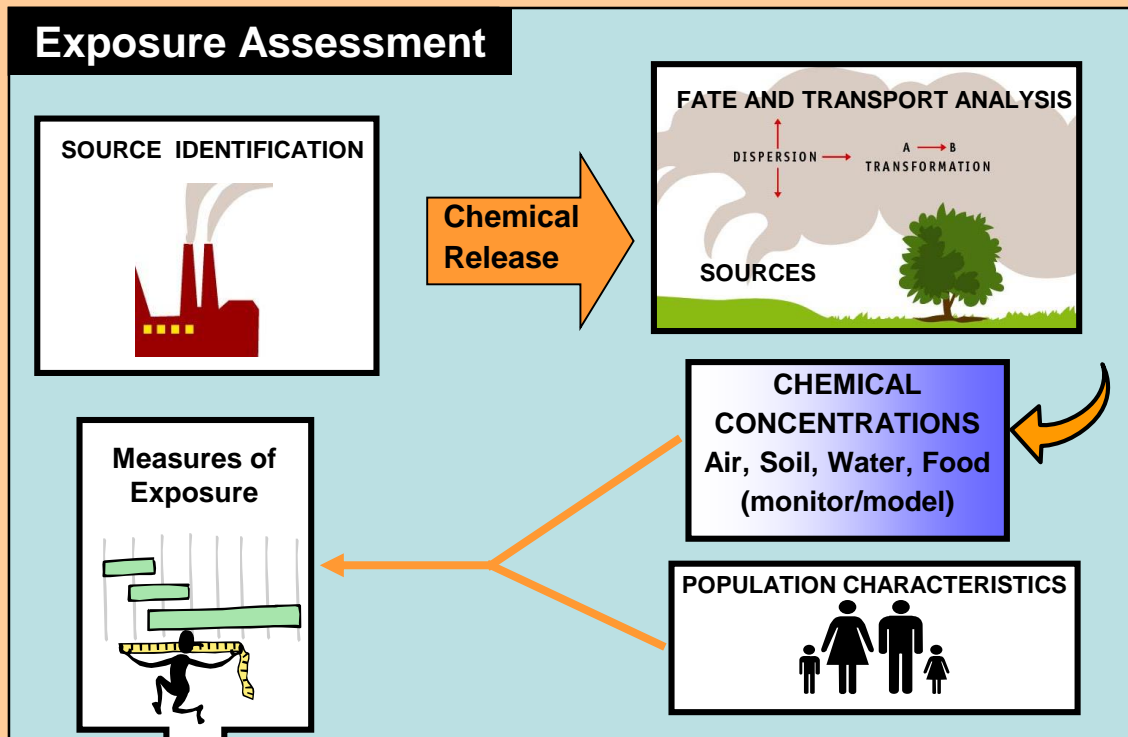




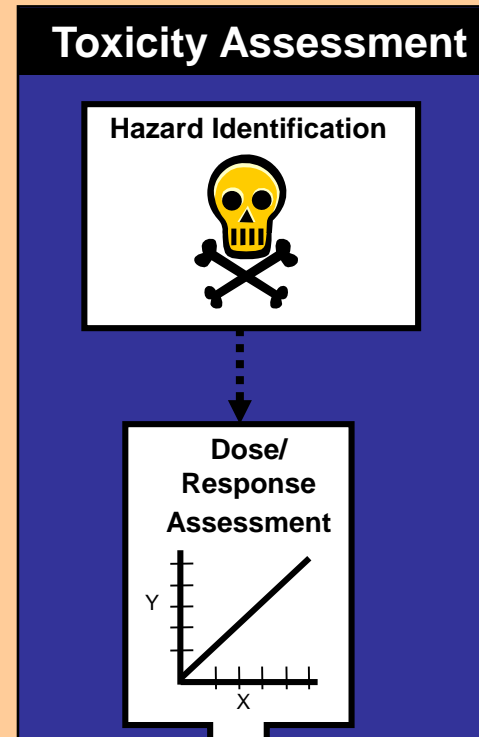
The Detailed Air Toxics Risk Assessment Process

Planning and Scoping

Exposure Assessment



Toxicity Assessment



Risk Characterization

EXPOSURE
information

DOSE/RESPONSE
information

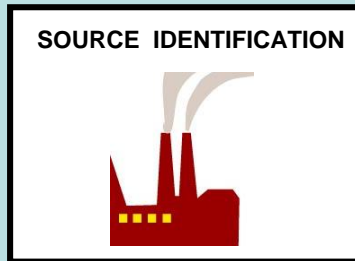
Quantitative and Qualitative Expressions of Risk/Uncertainty

The Detailed Air Toxics Risk Assessment Process

Planning and Scoping



Exposure Assessment



Chemical
Release

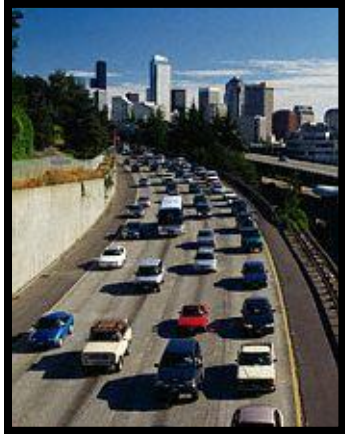
Toxicity Assessment

Risk Characterization

Air Release Sources

Mobile Sources

- On-Road
- Off-Road



Major Sources

≥ 10 tons per year (TPY) of any one HAP or ≥ 25 TPY of a combination of HAPs



Area Sources

Examples:

- Gasoline stations
- Dry cleaners
- Car painting shops
- Small electroplaters

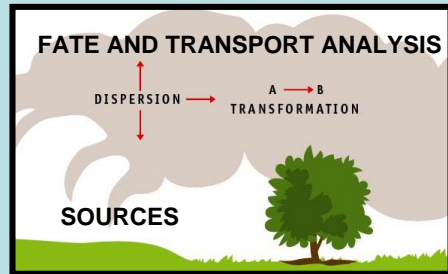
< 10 tons per year of a single air toxic, or < 25 tons per year of a combination of air toxics



The Detailed Air Toxics Risk Assessment Process

Planning and Scoping ✓

Exposure Assessment



**CHEMICAL
CONCENTRATIONS**
Air, Soil, Water, Food
(monitor/model)



Toxicity Assessment

Risk Characterization

Ambient Air Toxic Monitoring Data

AirData

- ▢ Provides access to monitoring data for criteria pollutants (<https://www.epa.gov/outdoor-air-quality-data>) and air toxics (<https://aqs.epa.gov/api>)

Ambient Monitoring Technology Information Center (AMTIC)

- ▢ Information and files on ambient air quality monitoring programs
- ▢ Details on monitoring methods
- ▢ Documents and articles
- ▢ Information on air quality trends and nonattainment areas
- ▢ Federal regulations related to ambient air quality monitoring

<https://www.epa.gov/amtic>

State websites



Dispersion Modeling Data

SCREEN 3

- Easiest to use, predicts conservative 1-hr concentrations

ISCST/ISCLT

- Regulatory “workhorse” model, 1-hr to annual average, best with source-specific data
- ISCST2 is dispersion model in HEM exposure model

AERMOD

- Soon to replace ISCST model, better in elevated terrain and complex meteorology. For criteria pollutants

CALPUFF

- Grid model, very data intensive, best for complex terrain

CMAQ

- Grid model, very data intensive, includes complex photochemistry

MOBILE 6

- Used for on-road mobile sources

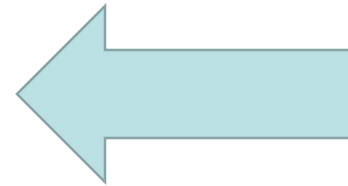


Monitoring/Modeling Data

Monitoring Data

Preference Requirements

- Typically 1-year
- Multiple Locations
- Including Background Samples
- Duplicates
- QA/QC'ed



Focus on
Monitoring Data

Modeling Data

Preference Requirements

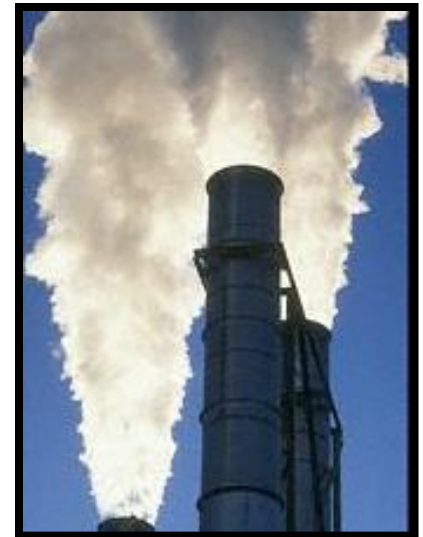
- Multiple Years (1 yr min)
- May include many sources
- Model to population locations (dispersion)

Exposure Point Concentration

The Exposure Point Concentration (EC) represents the concentration of the chemical in air (in $\mu\text{g}/\text{m}^3$) at the point of exposure.

For Chronic inhalation exposures, the 95% Upper Confidence Limit on the Mean is used either from modeling or monitoring.

<https://www.epa.gov/land-research/proucl-software>



The Detailed Air Toxics Risk Assessment Process

Planning and Scoping ✓

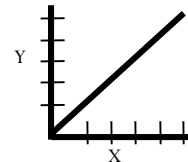
Exposure Assessment ✓

Toxicity Assessment

Hazard Identification

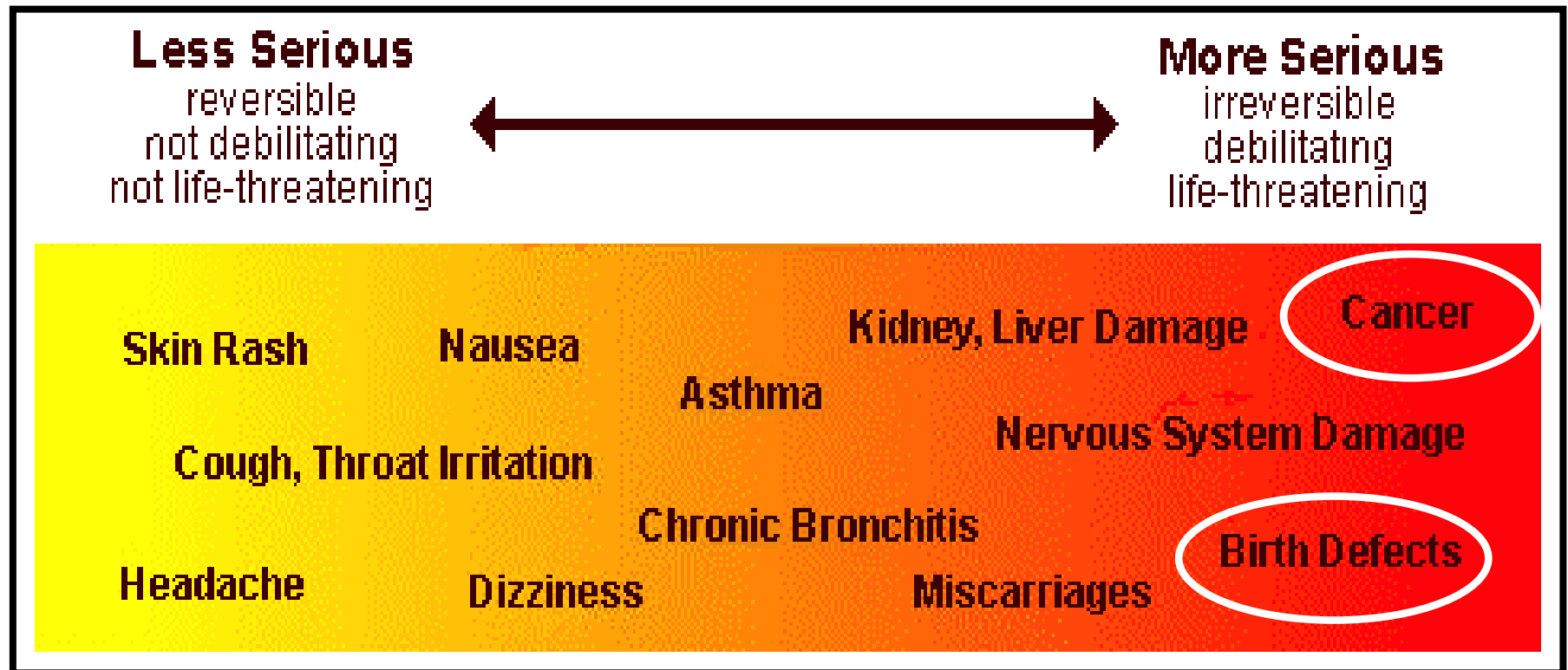


Dose/
Response
Assessment



Risk Characterization

Range of “non-Death” Effects



How are Toxicity Data Derived?

Toxicity Endpoints are Defined Using...

Data on adverse biologic effects usually generated through...

- Epidemiological studies
- Invivo biologic assays
- Invitro assays
- Structure-activity relationships (SAR)



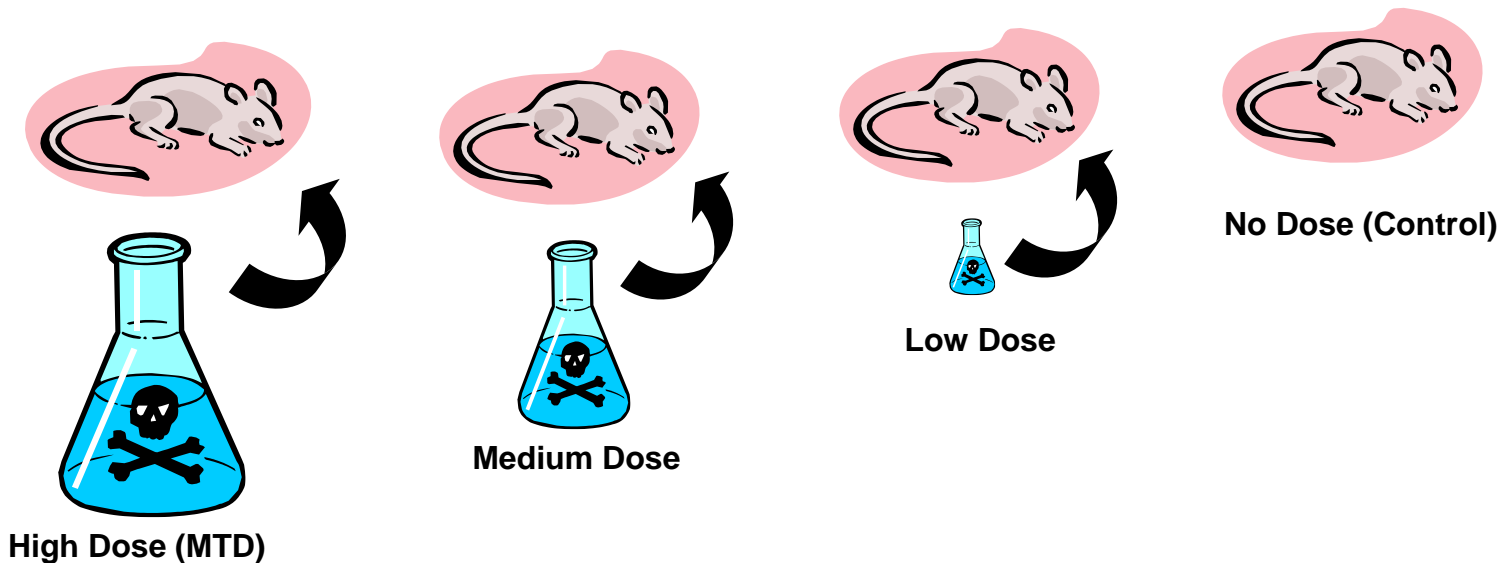
Human
Epidemiological
Studies



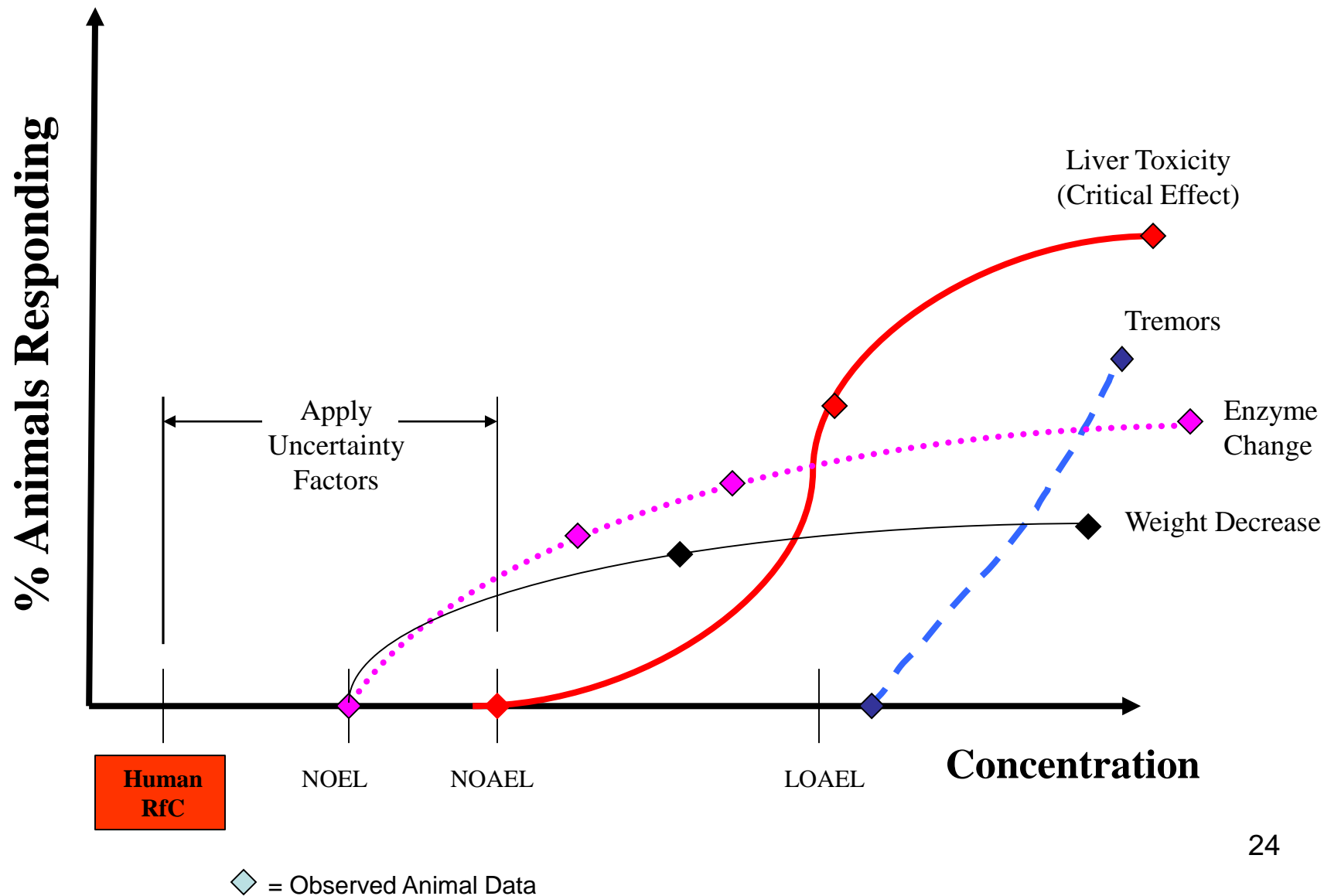
Laboratory Animal
Experiments

***In vivo* Rodent Bioassays**

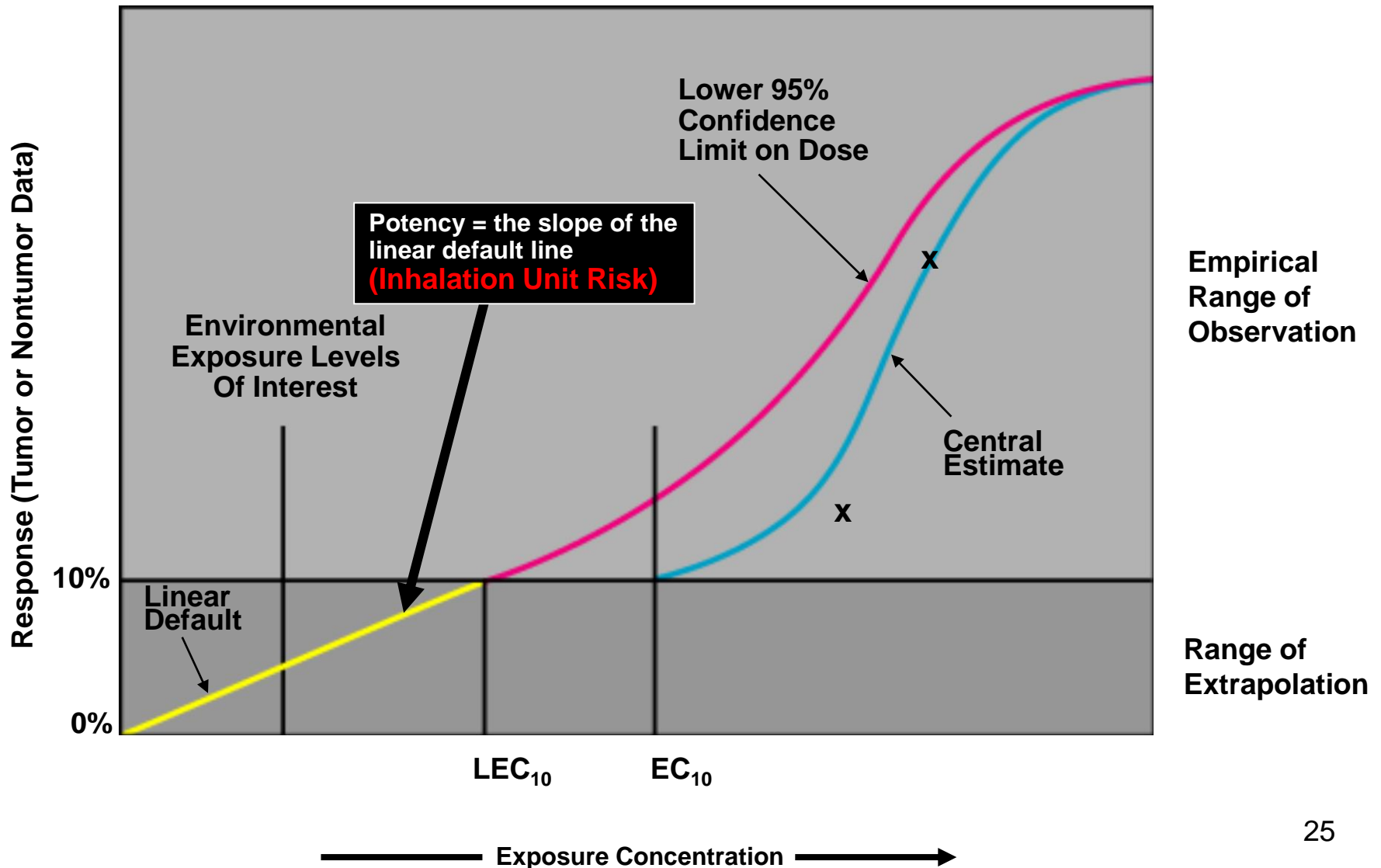
- Two species, both sexes (usually rats and mice)
- At least 50 animals in each group
- Expose from ~6 weeks through full lifespan (~24 mo.)
 - Dose at Maximum Tolerated Dose (MTD), fractions of MTD, and control (no dose)
 - Route of exposure similar to human exposure
- Observe outcomes (animals are sacrificed)



Dose-Response: Non-cancer



Dose-Response: Cancer



Sources of Toxicity Data

There are many choices

- EPA IRIS database
- California Hotspots program
- ATSDR MRLs
- NCEA provisional values
- EPA HEAST
- Open literature
- Etc.

Which value should we use?



Office of Air Quality, Planning and Standards:

<https://www.epa.gov/fera/dose-response-assessment-tables>

Tox21: High Speed Robot Screening System

- **Multiple Concentration (up to 15 per chemical)**
- **Uses 1536 microtiter plates to test 1408 samples plus neg. & pos. controls**
- **Each plate represents 1 concentration**
- **100 plates analyzed per day**
- **2800 compounds in 50 runs**

Overall: 1 million samples per week

Quantitative High Throughput Screening Assay



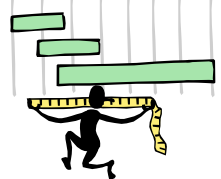
Phase 1: 2,800 Chemicals have already been screened

The Detailed Air Toxics Risk Assessment Process

Planning and Scoping ✓

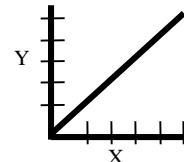
Exposure Assessment ✓

Measures of Exposure



Toxicity Assessment ✓

Dose/
Response
Assessment



Risk Characterization

EXPOSURE
information

DOSE/RESPONSE
information

Inhalation Non-Cancer Hazard

How do you usually calculate it?

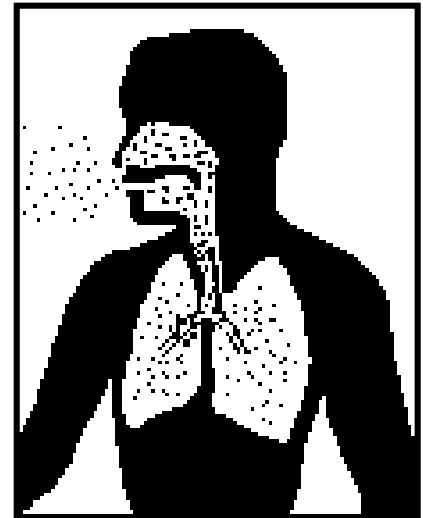
The basic equation for calculating hazard from breathing an air toxic that causes a non-cancer effect is:

$$\text{Hazard Quotient} = \text{EC} / \text{RfC}$$

Where:

EC = concentration of the chemical in air at the point of exposure (ug/m^3)

RfC = Reference Concentration (ug/m^3)

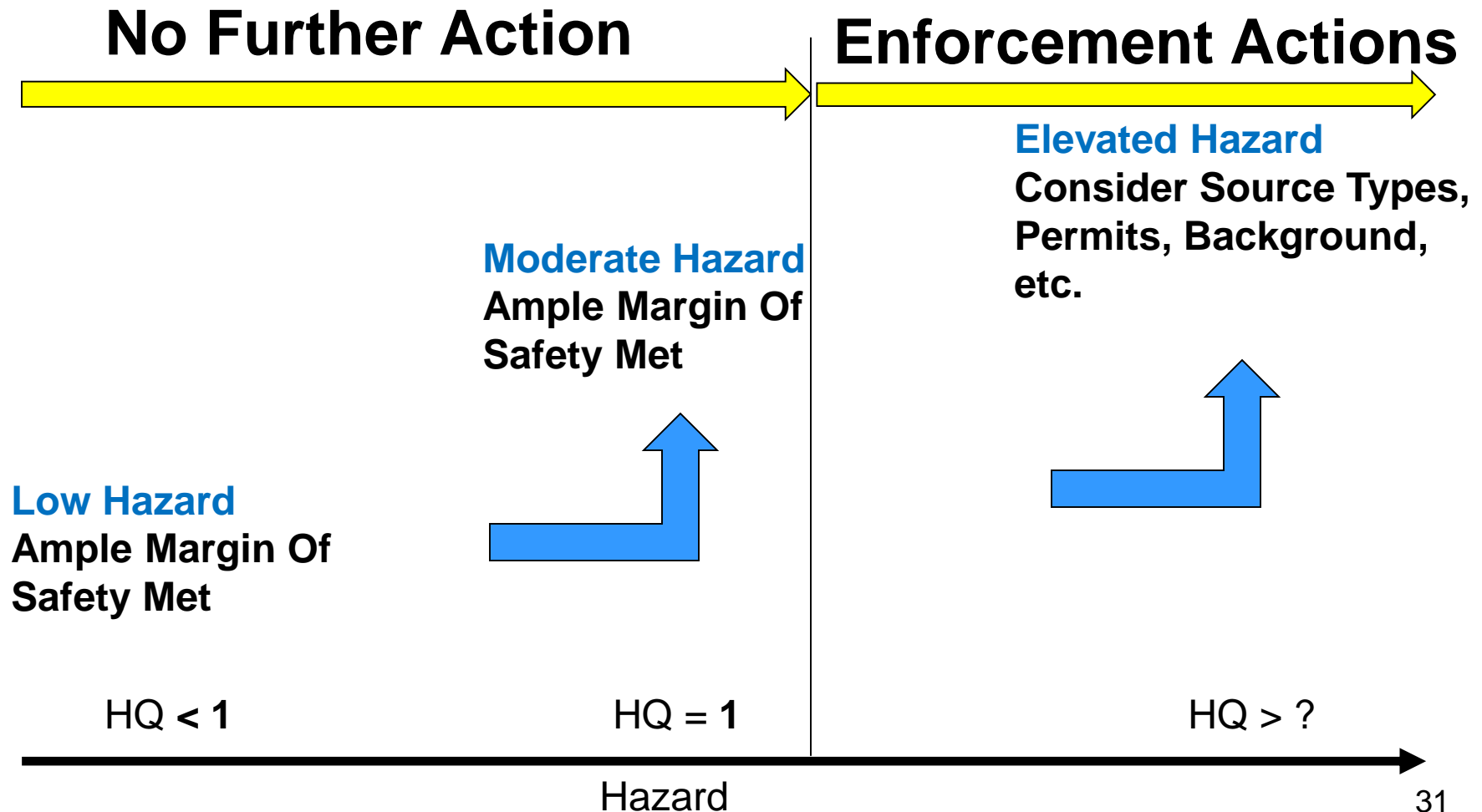


Definition: Non-cancer Hazard

A Reference Concentration (RfCs) is an estimate with uncertainty spanning perhaps an order of magnitude that is safe for continuous lifetime inhalation exposure for human populations (including sensitive subgroups). A Hazard Quotient results from a conservative comparison of the lifetime safe limit (RfC) to an exposure concentration.

How Is This Applied in Air Toxics Hazards?

For non-Cancer...



Inhalation Cancer Risk

How do you usually calculate it?

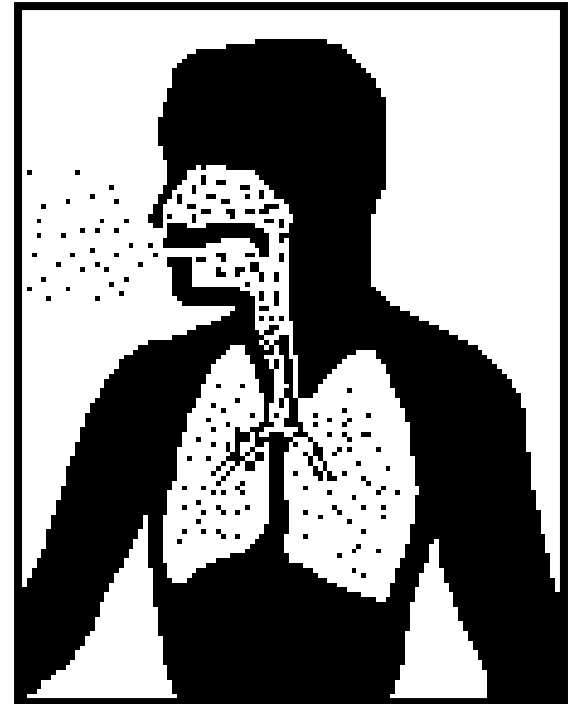
The basic equation for calculating risk from breathing a carcinogenic air toxic is:

$$\text{Risk} = \text{EC} \times \text{IUR}$$

Where:

EC = concentration of the chemical in air at the point of exposure (ug/m^3)

IUR = Inhalation Unit Risk
($\text{risk}/\text{ug}/\text{m}^3$)

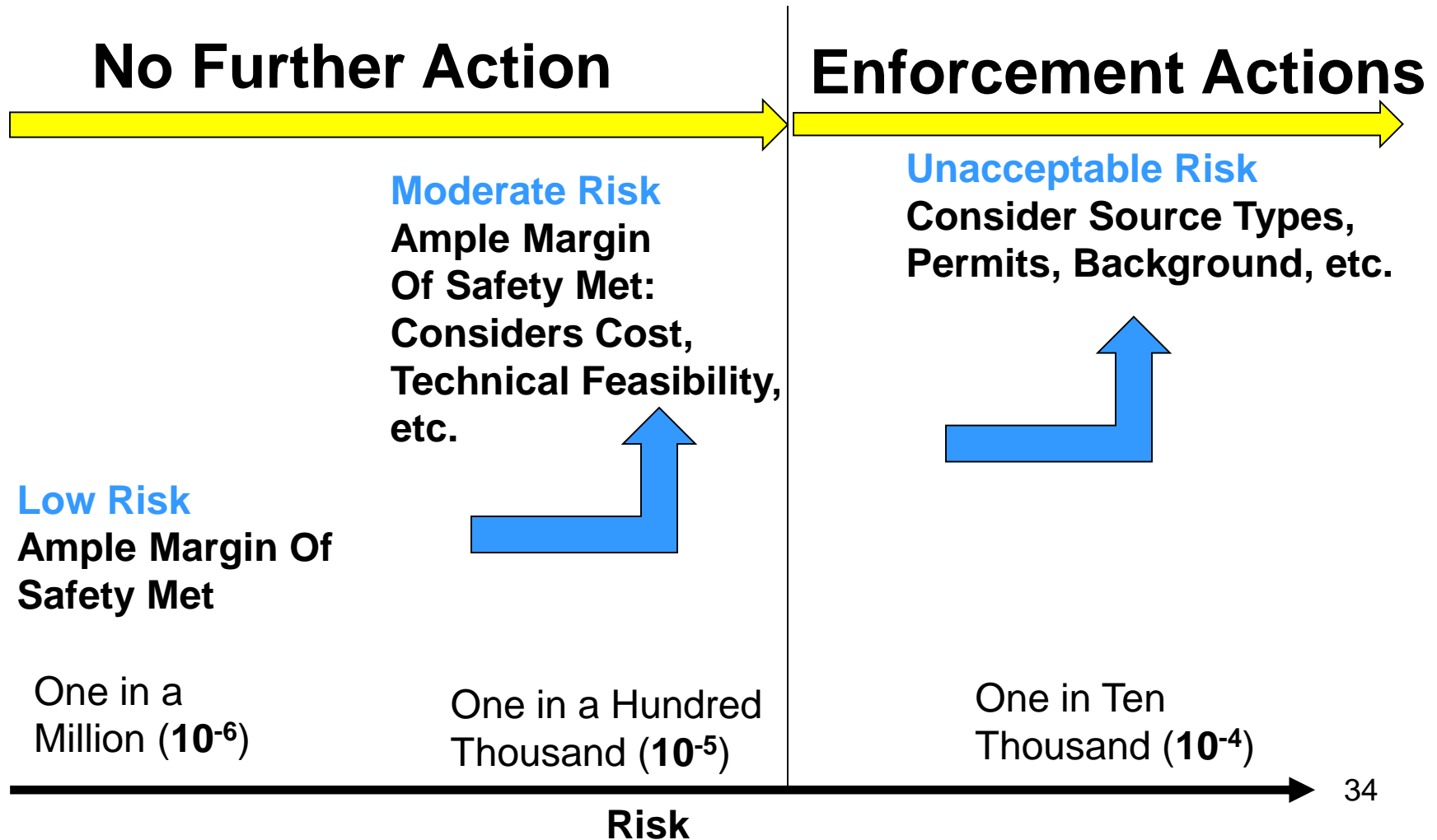


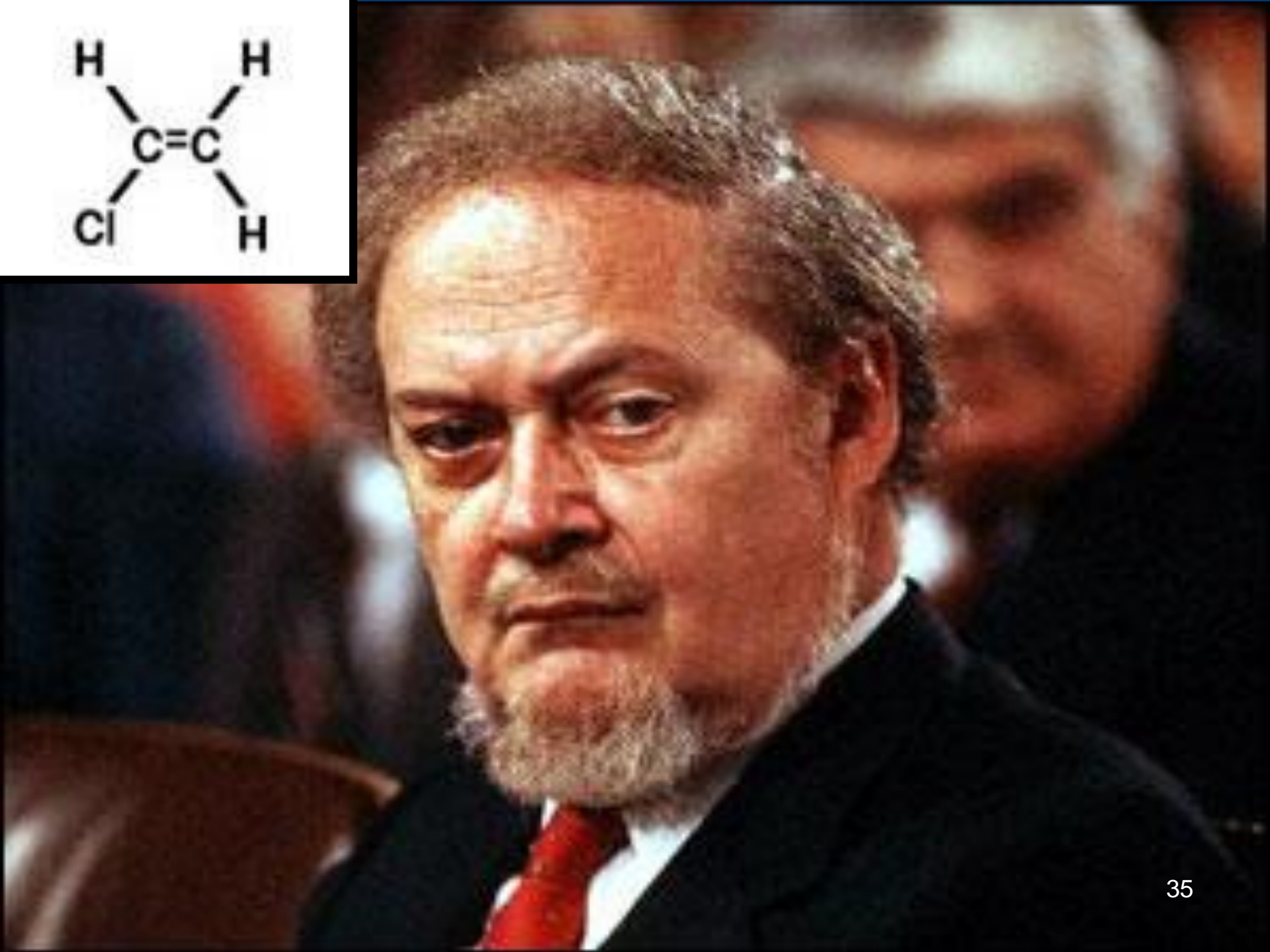
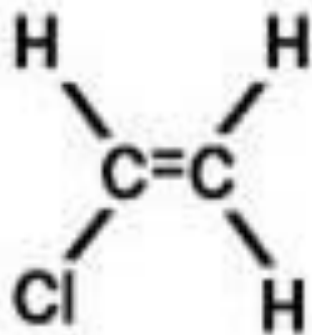
Definition: 1 in a Million Cancer Risk

A risk level of 1 in a million implies a likelihood that one person, out of one million equally exposed people would contract one additional cancer (additional to the background cancer rate of 1 in 3) if exposed continuously (24/7) to the specific concentration over 70 years (an assumed lifetime). This calculated risk would be an excess cancer risk, i.e., risks that are over and above the background cancer risks experienced due to non-air toxics causes.

How Is This Applied to Air Toxics Risks?

For Cancer...





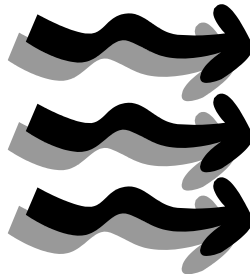
Ample Margin of Safety

2nd Step

Determine “ample margin of safety”

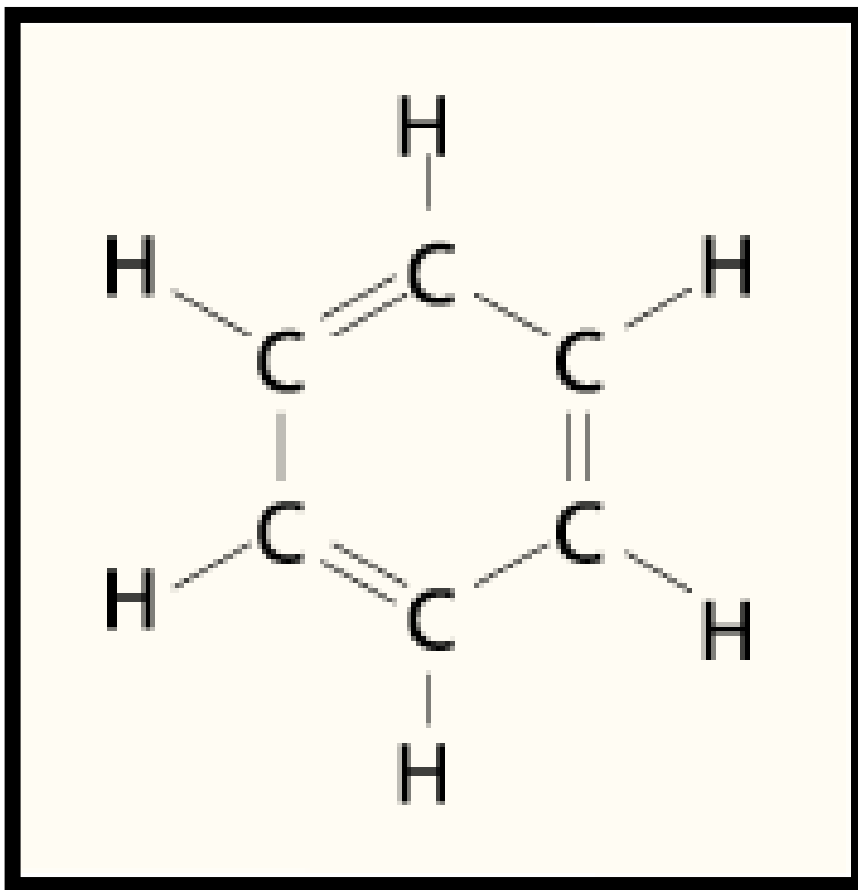
- Once you determine what a ‘safe’ emission level is, set the regulation to allow less emissions
- This will provide an “ample margin,” beyond what is “safe”

SAFE



**REALLY
SAFE!**

First Applied MOS to the 1989 NESHAP Standard



Benzene

1×10^{-6}

1×10^{-4}



Low Risk
Acceptable

High Risk
Unacceptable

Uncertainty Assessment Focal Areas

□ Exposure Assessment Uncertainties

Use of Default Assumptions O/U
Sampling Inadequacies/Issues U
Sample Collection: 24-hour Sample Every 6-days U
95% UCL O/U
½ DL for non-Detects O/U
High DL Issues U
1-yr Minimum Sampling Duration U
Detection Frequency 10% U
Model Applicability and Assumptions O/U
Likelihood that Exposure Pathways (Ingest.) are Occurring O/U
Sources and Chemicals not Included in the Assessment U

□ Toxicity Assessment Uncertainties

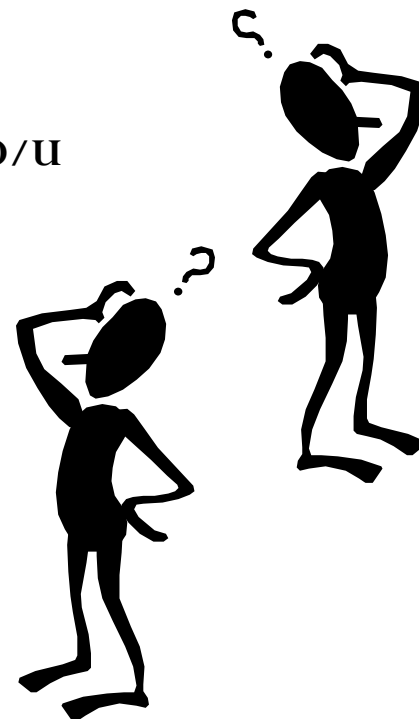
Missing Acute Standards U
Animal to Human Extrapolation O/U
Sensitive Subpopulation Adjustment O/U
Route to Route Extrapolation O/U
Missing/Inadequate Toxicity Database O/U
Mixtures Approaches O/U
Chemicals with no Toxicity Values U
TOSHI Analyses O/U

□ Risk Characterization Uncertainties

Risk/Hazard Additivity O/U

O=Over Predicts Risk

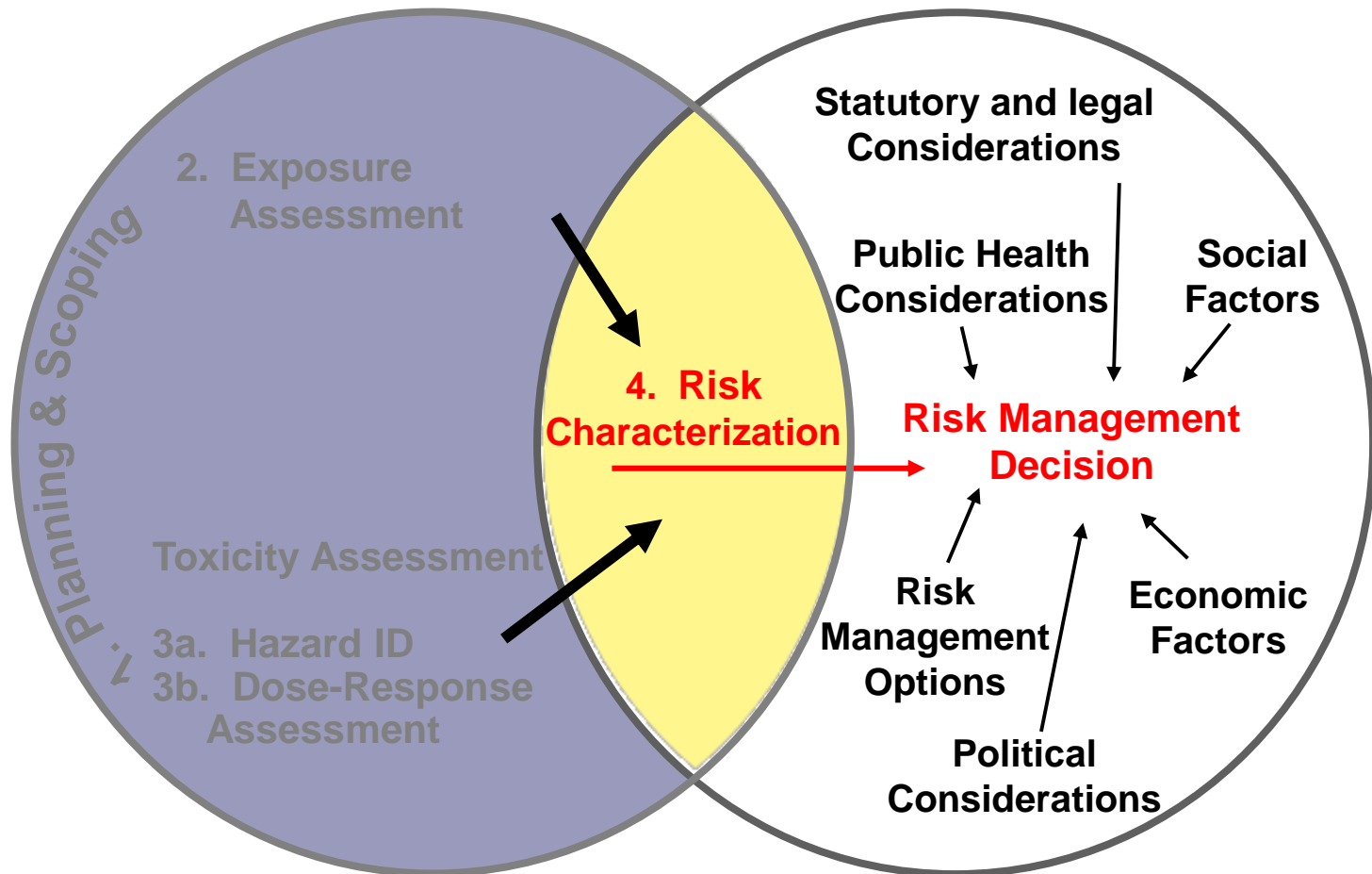
U=Under Predicts Risk



Risk Management and Decision Making

Risk Assessment

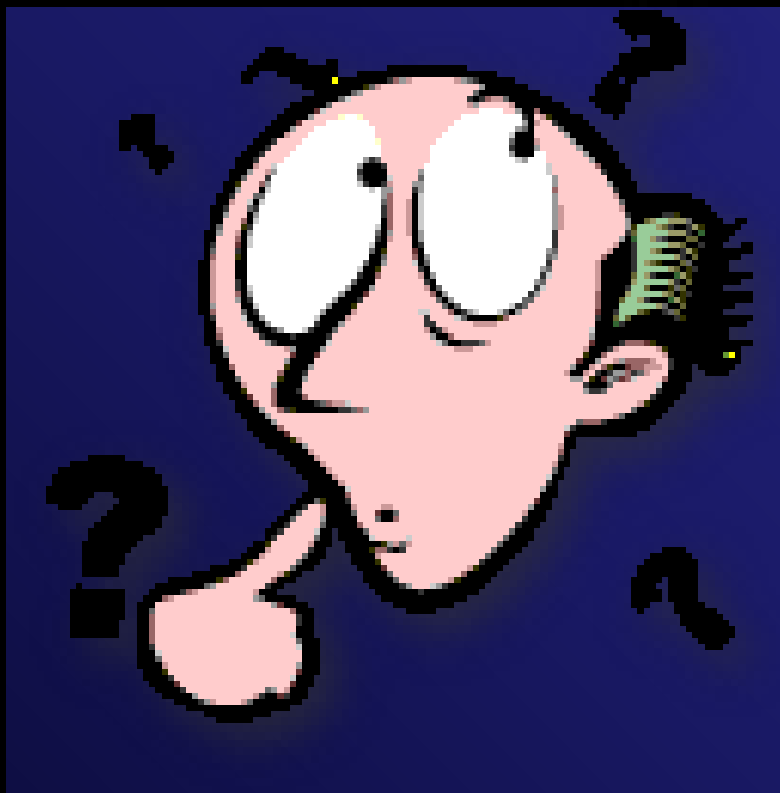
Risk Management



Developing a RA!?!?

Dose-
Response

Risk
Paradigm



Risk
Characterization

Templates are Available...

Toxicity
Testing